Remarks/Arguments

Claims 1-37 constitute the pending claims in the present application. Amendments presented in this response are made solely to expedite prosecution of the claims in the present application. Applicant reserves the right to prosecute claims of similar or differing scope in subsequent applications. Applicant respectfully requests reconsideration in view of the following remarks.

Rejections under 35 U.S.C. § 102

Claims 1-2, 9-23, 25-28, 31-32, 35, and 37-46 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,334,856 ("the '856 patent") to Allen et al. Applicant respectfully traverse the rejection with respect to the application as amended. Applicants have amended the specification to claim the benefit of the filing date of the '856 patent. Applicants submit that: (1) the two applications were copending at the time the present application was filed, and (2) the time limit in which to claim benefit of an earlier application does not apply to the present application, filed December 2, 1999. Applicants respectfully direct the Examiner's attention to MPEP 201.11(V) which states that the "time period requirement under 37 CFR 1.78(a)(2) and (a)(5) is only applicable to utility or plant applications filed on or after November 29, 2000. Accordingly, the '856 patent is not prior art under 35 U.S.C. § 102. Applicants respectfully request reconsideration and withdrawal of the rejections.

Rejections under 35 U.S.C. § 103

Claims 3-5, 7, 29, and 33-34 are rejected under 35 U.S.C. § 103(a) as being obvious over the '856 patent to Allen et al. and further in view of U.S. Patent 5,364,374 ("the '374 patent") to Morrison et al.

Claims 3, 6, and 8 are rejected under 35 U.S.C. § 103(a) as being obvious over the '856 patent to Allen et al. and further in view of U.S. Patent 4,703,761 ("the '761 patent") to Rathbone et al.

Claims 24 is rejected under 35 U.S.C. § 103(a) as being obvious over the '856 patent to Allen et al. and further in view of International Application Publication WO 98/00193 ("the '193 publication") to Eppstein.

Applicants have amended the specification to claim the benefit of the filing date of the '856 patent. Accordingly, the '856 patent is not available as prior art under 35 U.S.C. § 103. Applicants respectfully request reconsideration and withdrawal of the rejections.

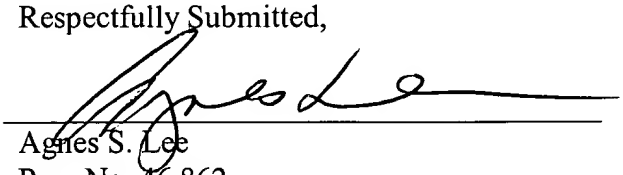
Double Patenting Rejection

Claims 1-4, 6, 27, 29-30, 36, 38-41, and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 9 of U.S. Patent 6,503,231 ("the '231 patent") to Prausnitz et al. in view of Japanese Patent Application Publication JP07132119A ("the '119 publication") to Yoshihiko. Applicants will file a terminal disclaimer to overcome the rejection upon indication of allowable subject matter. Applicants respectfully request reconsideration and withdrawal of the double patenting rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,



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This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (previously amended) A device for collecting a sample of a biological fluid comprising:

one or more hollow or porous microneedles, each having a base end and a tip, wherein the microneedle has a length between 500 μm and 1 mm and a width between about 1 μm and 500 μm;

a substrate to which the base of the microneedle is attached or integrated, wherein the microneedle is perpendicular to or extends at an angle from a surface of the substrate; and

at least one collection chamber which is selectably in fluid communication with the base end of the microneedle.

2. (previously amended) The device of claim 1 further comprising a means for inducing transport of a biological fluid or component thereof into the collection chamber.

3. (original) The device of claim 2 wherein the pressure within the collection chamber can selectively be reduced.

4. (original) The device of claim 3 wherein the pressure reduction is induced by expanding the internal volume of the collection chamber.

5. (original) The device of claim 4 wherein the collection chamber is a standard or Luer-lock syringe.

6. (original) The device of claim 3 wherein the collection chamber comprises an upper portion which is formed of a material which is deformable.

7. (previously amended) The device of claim 3 wherein the means for inducing transport comprises a plunger movably secured to the substrate, wherein the plunger can deform the collection chamber.

8. (previously amended) The device of claim 6 wherein the collection chamber comprises a one-way valve.

9. (original) The device of claim 1 wherein the collection chamber comprises a plurality of compartments.

10. (original) The device of claim 1 comprising a three dimensional array of microneedles.

11. (previously amended) The device of claim 1 further comprising an adhesive material for securing the device to a biological barrier surface during fluid withdrawal or sensing.

12. (original) The device of claim 1 further comprising a means for controlling flow through the microneedle.

13. (original) The device of claim 12 wherein the means for controlling flow is a fracturable or removable barrier which is interposed between the collection chamber and base of the microneedle.

14. (original) The device of claim 1 further comprising a sensor in communication with the collection chamber.

15. (previously amended) A device for sensing an analyte in a biological fluid comprising:

one or more microneedles, each having a base end and a tip, wherein the microneedle has a length between about 500 μm and 1 mm and a width between about 1 μm and 500 μm;

a substrate to which the base of the microneedle is attached or integrated, wherein the microneedle is perpendicular to or extends at an angle from a surface of the substrate; and

at least one sensor which is selectably in communication with the microneedle.

16. (previously amended) The device of claim 15 wherein the sensor comprises:

a chemical or biochemical agent that react with an analyte, and

electrochemical or optical transducers which measure the reaction of the agent and the analyte.

17. (original) The device of claim 16 wherein the agent is an enzyme selected from the group consisting of glucose oxidase, glucose dehydrogensase, and combinations thereof.

18. (original) The device of claim 15 further comprising an electronics package in communication with the sensor.

19. (original) The device of claim 15 for insertion of the microneedles in skin and sensing of glucose.

20. (previously amended) A device for sensing an analyte in a biological fluid ~~comprising:~~

one or more microneedles, each having a base end and a tip, wherein the microneedle has a length of between 500 μm and 1 mm and a width between about 1 μm and 500 μm; and

a substrate to which the base of the microneedle is attached or integrated,

wherein the microneedle is perpendicular to or extends at an angle from a surface of the substrate;

wherein at least one of the microneedles is or comprises a sensor.

21. (currently amended) The device of claim 20 wherein the sensor comprises:

a chemical or biochemical agent that ~~react~~ reacts with an analyte, and

electrochemical or optical transducers which measure the reaction of the agent and analyte.

22. (original) The device of claim 20 further comprising an electronics package in communication with the sensor.

23. (original) The device of claim 20 for insertion of the microneedles in skin and sensing of glucose.

24. (original) The device of claim 1 wherein the collection chamber is adapted to receive and use glucose strips.

25. (original) The device of claim 1 wherein the microneedle is hollow and comprises at least one opening in the side of the microneedle.

26. (original) The device of claim 1 wherein the microneedle has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into the collection chamber.

27. (previously amended) A method for collecting a sample of a biological fluid or analyte therein, comprising the steps:

providing the device of claim 1;

inserting the microneedles of the device into a biological barrier comprising biological fluid; and

triggering the means for inducing to permit the transport of a quantity of the biological fluid or an analyte therein through the microneedles and into the collection chamber.

28. (previously amended) The method of claim 27 wherein the means for inducing is selected from the group consisting of capillary action, diffusion, mechanical pumps, electroosmosis, electrophoresis, convection, and combinations thereof.

29. (previously amended) The method of claim 27 wherein the means for inducing utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

30. (original) The method of claim 27 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

31. (currently amended) A method <u>for</u> sensing an analyte in a biological fluid, comprising the steps:

providing the device of claim 15;

inserting the microneedles into a biological barrier comprising biological fluid which contains an analyte; and

contacting the sensor with the biological fluid, thereby sensing the analyte.

32. (currently amended) The method of claim 31 wherein the device further comprises:

at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and

a means for inducing transport of the biological fluid or ~~component thereof~~ <u>an analyte therein</u> into the collection chamber,

wherein, after the microneedles are inserted, the means for inducing is triggered to draw the biological fluid or an analyte therein through the microneedles and into the collection chamber.

33. (previously amended) The method of claim 32 wherein the means for inducing utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

34. (original) The method of claim 33 wherein the pressure gradient is created by increasing the volume within the collection chamber.

35. (original) The method of claim 31 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

36. (original) The method of claim 27 for sensing glucose wherein the biological barrier is human skin.

37. (original) The method of claim 31 for sensing glucose wherein the biological barrier is human skin.

38. (previously presented) The device of claim 1 wherein the microneedle comprises a metal.

39. (previously presented) The device of claim 38 wherein the microneedle consists essentially of a metal.

40. (previously presented) The device of claim 1 wherein the microneedle is hollow.

41. (previously presented) The device of claim 1 wherein the microneedle is perpendicular to a surface of the substrate.

42. (previously presented) The device of claim 15 wherein the microneedle comprises a metal.

43. (previously presented) The device of claim 43 wherein the microneedle consists essentially of a metal.

44. (previously presented) The device of claim 15 wherein the microneedle is hollow.

45. (previously presented) The device of claim 15 wherein the microneedle is perpendicular to a surface of the substrate.

46. (previously presented) The device of claim 1 wherein the microneedle has a diameter between about 40 and 120 μm.